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K002229

510(k) Summary
for the ECLIPSE Systems, Inc. Wackers-Liu CQ™ Software
(per 21 CFR 807.92)

1. SPONSOR

ECLIPSE Systems, Inc.
540-15 East Main Street
Branford, Connecticut 06405

Contact Person: Mr. William Carroll
Telephone: 203-483-0665

2. DATE PREPARED: July 21, 2000

3. DEVICE NAME

Proprietary Name:	Wackers-Liu CQ™ Software
Common/Usual Name:	ECT Quantitative Analysis and image communication software
Classification Name:	Emission Computed Tomography System and Medical Image Communication Device

4. PREDICATE DEVICES

- CEqual (Nuccardiac Software) K972509
- SPECTEF (QGS) (GE) K954874

5. DEVICE DESCRIPTION

The Wackers-Liu CQ™ Software is currently a stand-alone software package. This product is the automated commercial version of a totally integrated and manually operated cardiac imaging analysis package developed by Drs. Wackers and Liu, and others at the Yale University Cardiovascular Nuclear Imaging Laboratory and described extensively in the peer-reviewed literature.

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6. INTENDED USE

The Wackers-Liu CQ™ Software is a stand-alone software package for quantification of emission computed tomography (ECT) myocardial perfusion images. The data generated by the Wackers-Liu CQ™ Software is intended to be used by the physician in addition to other complementary data in the evaluation of cardiac function and blood supply. It is not meant to replace or eliminate the physician's standard visual interpretation of the patient study or the integration of additional clinical and/or diagnostic information (patient history, stress and/or rest EKG, echocardiogram, etc.) prior to making any final clinical diagnostic or treatment decision. The Wackers-Liu CQ™ Software also allows for transmission of ECT images over the internet.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The claim of substantial equivalence is based on indications for use, operational principles, and technological characteristics. A side-by-side comparison of the Wackers-Liu CQ ™ Software to the cited predicate devices is provided in the Table F-1 below.

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Table F-1. Comparison of the Wackers-Liu CQ with Predicate Devices

Characteristic	ECLIPSE Systems, Inc. Wackers-Liu CQ	SPECTEF (QGS) K954874	Cequal K972509
Used to quantify ECT images	Yes	Yes	Yes
Automatic processing	Yes	Yes	Yes
Manual processing capability	Yes	Yes	Yes
Slice-by-slice viewing	Yes	Yes	No
3D imaging	Yes	Yes	No
Computes and displays left ventricular chamber volume	Yes	Yes	No
Computes and displays ejection fraction	Yes	Yes	No
Compares data to "normal" database	Yes	No	No
Display left ventricular endocardial/epicardial surfaces	Yes	Yes	No
Displays polar maps indicating perfusion	No	Yes	Yes
Displays wall thickening	Yes	Yes	No
Displays wall motion	Yes	Yes	No
Displays 3D rendered image of cardiac surfaces	Yes	Yes	No
Displays short axis, vertical long, and horizontal long slice data	Yes	Yes	No
Displays single data set or comparison of related data sets	Yes	No	Yes
Can be executed on most nuclear medical computers	Yes	Yes	Yes
Can be executed on PC and Macintosh computers	Yes	Yes	No

8. PERFORMANCE TESTING

Testing of the Wackers-Liu CQ™ Software demonstrates that the ECLIPSE Systems, Inc. Wackers-Liu CQ™ Software fulfills performance specifications and results are equivalent to those obtained with predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2000

Eclipse Systems, Inc.
c/o Rosina Robinson
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K002229
Wackers-Liu CQ™ Software
Dated: July 21, 2000
Received: July 24, 2000
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Robinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002229

Device Name: ECLIPSE Systems Inc. Wackers-Liu CQ™ Software

Indications For Use:

The Wackers-Liu CQ™ Software is a stand-alone software package for quantification of emission computed tomography (ECT) myocardial perfusion images. The data generated by the Wackers-Liu CQ™ Software is intended to be used by the physician along with other complementary data in the evaluation of cardiac function and blood supply. It is not meant to replace or eliminate the physician's standard visual interpretation of the patient study or the integration of additional clinical and/or diagnostic information (patient history, stress and/or rest EKG, echocardiogram, etc.) prior to making any final clinical diagnostic or treatment decision. The Wackers-Liu CQ™ Software also allows for transmission of ECT images over the internet.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002229

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)